

### REMARKS

Applicant respectfully requests withdrawal of the rejection of record and a Notice of Allowability. Should the Examiner wish to maintain the current rejection or a similar rejection, Applicant must request the issuance of a new, non-final Office Action that sets out with specificity the grounds of rejection and support for that rejection. The Office Action mailed April 9, 2009 is insufficient in a number of critical areas. The Office Action does not set forth a *prima facie* case of obviousness; does not clearly define a rejection; does not address the factual inquiry necessitated in an obvious analysis; does not address all of the elements of even the independent claims; and does not provide support for the rejection that is sufficient for Applicant to appreciate the Examiner's intent and application of the references.

Ostensibly, the Examiner has rejected claims 1-20 under 35 USC 103(a) as being unpatentable over Pedersen in view of Tu. In support of the rejection, the action includes a (verbatim) restatement from a previous office action characterizing the Pedersen reference (as applied to claims different than those currently pending); states that "Pedersen discloses the invention as substantially claimed" but Tu "better teaches" certain elements. "*Therefore it would have been obvious*" to modify Pederson based on Tu. It is unclear to applicant how the existence of a second reference that "better teaches" something purportedly disclosed in a first reference, renders modification of the first reference obvious. The Examiner's position on the content of the references (both positive and negative), the proposed combination, the motivation for such a combination, and how such a combination would teach the *claims as a whole* is absent from the written record. The written record is simply ambiguous as to what the Examiner sees in each reference with respect to the claims.

Accordingly, Applicant is unable to determine or reasonably infer the Examiner's intent or meaning. Is the Examiner, in effect, continuing to improperly consider Pedersen to be anticipatory? If so, then the rejection under section 103(a) and the citation of Tu is improper. If this is an obviousness rejection under section 103(a), then what features of the claims are being acknowledged by the Examiner as being absent? Where is the Graham analysis? If Tu "better teaches" the claimed feature(s), why is *that* reference not the primary reference or the basis of an anticipation rejection? Hopefully, the Examiner can appreciate and acknowledge that the written

record is completely insufficient with respect to the treatment of the claims, the analysis of the art, and the purported combination.

Applicant certainly appreciates the irony in the Examiner's contention that the "modification" of the disposable urinary catheter of Pedersen to be more like the RF ablation catheter of Tu used in cardiac surgery, with its multiple electrodes, internal wiring, steering cables, steering mechanism, wiring connectors and reusable handle would be "motivated" on the basis of "decreasing the cost" of the disposable urinary catheter. Applicant respectfully traverses.

Applicant respectfully asserts that the pending claims distinguish over the art or record, alone or combination. Further, Applicant respectfully requests notification of the same.

Claim 1 includes a catheter assembly that has a container, a handle with a sleeve that surrounds the container, a catheter that fits into the container and where the handle and the catheter have respective locking mechanisms that mechanically interlock the two components together.

The handle of Pedersen (as used by the Examiner) does not surround a portion of container, does not interlock with the catheter, and does not have an interlocking mechanism to mechanically interlock with a corresponding mechanism on the catheter. What Pedersen does teach is separating a portion of the housing to use as a gripping mechanism to medially engage the lubricated catheter.

Tu teaches an RF ablation catheter (2 -3 feet long) used in cardiac surgery. A catheter having multiple electrodes, coupled wiring, steering wires and a steering mechanism is attached to a reusable handle 5. There is no need, teaching or relevance in having a package with a catheter, a container, and a handle that surround the container.

Accordingly, it is wholly unclear how the Examiner is interpreting these references to arrive at the present claims. Applicant respectfully asserts that Pedersen fails to teach the handle as claimed and in particular how such a handle couples with the container (as claimed). If the handle of Tu were utilized, this would take the combination even further away from the claimed device as Tu *does not teach, contemplate, or technically permit* the handle as presently claimed, let alone one where the handle surrounds the container and also has an interlocking mechanism to engage a corresponding mechanism on the catheter.

That Examiner may not simply assert that since the RF catheter releasably engages Tu's handle, such a configuration would be relevant to Pedersen. It would not. The Pedersen product is a combined package and gripping mechanism; adding the features of Tu would hinder the use of the Pedersen device in its intended manner and for its intended purpose. In Pedersen, the catheter is gripped along the lubricated shaft with portion 10; not engaged from the end. Thus, the Examiner would effectively have to redesign the entirety of the Petersen product, without any support from any cited reference, based only upon hindsight and Applicant's claims as a roadmap, in order to incorporate the Tu features. This cannot be reasonably supported and is certainly not taught or suggested by the art.

The Examiner states that "by the modification of Pedersen with Tu, the handle 5 of Tu is capable of being attached to the container 4 of Pedersen." Even if true, this is irrelevant; capability does not lead to a finding of obviousness. Further, if the handle 5 is used in Pedersen as asserted by the Examiner, then the remaining elements of the claims are even further distinguished (e.g., the handle surrounding the container).

The Examiner then states that "the catheter handle is shorter than said container or shorter than said catheter element, Fig 1 of Tu." It is wholly unclear what the meaning or relevance of this is, or what the Examiner may have intended to provide in this section.

Applicant respectfully asserts that elements of the claims have not been addressed, the references have not been fully applied or addressed, and no *prima facie* rejection has been provided in the record. Accordingly, should the Examiner refuse to acknowledge the allowability of the claims, a new, non-final office action must be provided that fully and completely addresses all of the elements of the present claims and sets out a comprehensive and fully articulated basis for a rejection based upon the relevant patent law and rules of practice.

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### **CONCLUSION**

Applicant respectfully asserts that the pending claims are in condition for allowance and notice of the same is respectfully requested. Should any issues remain outstanding, the Examiner is respectfully urged to telephone the undersigned. No additional fee are believed due at this time; however, the office is authorized to charge any fees actually due and credit any overpayment to deposit account 50-4439.

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Respectfully submitted,  
Pedersen et al.

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